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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/640,041	08/15/00	KAVANAUGH W	1615.002/200

027476
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HM12/1030

EXAMINER	
JAMROZ, M	
ART UNIT	PAPER NUMBER
1644	8

DATE MAILED: 10/30/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/640,041	Applicant(s) KAVANAUGH ET AL.	
	Examiner Margaret E Jamroz	Art Unit 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-37 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-37 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *notice to comply* .

DETAILED ACTION

1. The location of your application in the PTO has changed. To aid in correlating papers for this application, all further correspondence regarding this application should be directed to Megan Jamroz in Art Unit 1644, Group 1640, Technology Center 1600.

Sequence Compliance

2. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

Please review the attached "Raw Sequence Listing Error Report". Applicant is reminded to amend the specification (including the Brief Description of Drawings) and claims as appropriate to reflect compliance with the Sequence Rules.

Restriction Requirement

3. The following is noted:

Claim 24 recites a method of modulating by administering an effective amount of a composition that utilize different products: a polypeptide; and an antibody. Antibodies and polypeptides differ with respect to their structure, a person of ordinary skill in the art would not envision one in view of the other. In addition, they differ in mode of action. Therefore, the restriction has been set forth for each as separate groups, irrespective of the format of the claims.

Claims 19-21 recite an antibody that binds polypeptides of different specificities: mouse (SEQ ID NO: 2) and human (SEQ ID NO: 4). The polypeptides differ with respect to their structures; a person of ordinary skill in the art would not envision one in view of the other. In addition, they differ in mode of action. Therefore, the restriction has been set forth for each as separate groups, irrespective of the format of the claims.

Dependent claims 32-34 recite a method for treating with a composition comprising a polynucleotide as it reads in an anti-sense construct, a ribozyme, and a retroviral vector comprising a promoter. Anti-sense constructs, ribozymes, and retroviral vectors comprising promoters differ with respect to their structures; a person of ordinary skill in the art would not envision one in view of the other. In addition, they differ in mode of action. Therefore, the restriction has been set forth for each as separate groups, irrespective of the format of the claims.

It is also noted:

The polynuceotide sequences from claim 1 (SEQ ID NOS: 2 and 4) recited in claims 32-24 cannot be an anti-sense contruct, a ribozyme, and a retroviral vector comprising a promoter.

The claims improperly recite a polynucleotide sequence as they read on a ribozyme (polypeptide).

4. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1-9 and 14, drawn to an isolated and purified nucleotide sequence (SEQ ID NO: 2); a vector, a method of making the vector, a host cell, a method of making the host cell, and a method of producing the polypeptide, classified in Class 536, subclass 23.5; Class 435, subclasses 69.1, 455, 252.3, and 320.1; Class 514, subclass 44.

II. Claims 1-9 and 14, drawn to an isolated and purified nucleotide sequence (SEQ ID NO: 4); a vector, a method of making the vector, a host cell, a method of making the host cell, and a method of producing the polypeptide, classified in Class 536, subclass 23.5; Class 435, subclasses 69.1, 455, 252.3, and 320.1; Class 514, subclass 44.

III. Claims 10-13 and 15-18, drawn to a polypeptide comprising SEQ ID NO: 2, fragments and compositions thereof; classified in Class 514, subclass 2.

IV. Claims 10-13 and 15-18, drawn to a polypeptide comprising SEQ ID NO: 4, fragments and compositions thereof; classified in Class 530, subclasses 300 and 350.

V. Claims 19-21, drawn to an antibody as it reads on SEQ ID NO: 2; classified in Class 530, subclass 387.1.

VI. Claims 19-21, drawn to an antibody as it reads on SEQ ID NO: 4; classified in Class 530, subclass 387.1.

VII. Claims 22 and 26, drawn to a method of diagnosing with an antibody as it reads on SEQ ID NO: 2, classified in Class 435, subclass 7.1.

VIII. Claims 22 and 26, drawn to a method of diagnosing with an antibody as it reads on SEQ ID NO: 4, classified in Class 435, subclass 7.1.

IX. Claim 23, drawn to method of diagnosing with a nucleotide (SEQ ID NO: 2); classified in Class 435, subclass 6.

X. Claim 23, drawn to method of diagnosing with a nucleotide (SEQ ID NO: 4); classified in Class 435, subclass 6.

XI. Claims 24, 26, 35, and 37, drawn to a method of modulating with a polypeptide as it reads on SEQ ID NO: 2; classified in Class 514, subclass 8.

XII. Claims 24, 26, 35, and 37, drawn to a method of modulating with a polypeptide as it reads on SEQ ID NO: 4; classified in Class 514, subclass 8.

XIII. Claims 24, 26, 35, and 36, drawn to a method of modulating with an antibody as it reads on SEQ ID NO: 2; classified in Class 424, subclass 130.1.

XIV. Claims 24, 26, 35, and 36, drawn to a method of modulating with an antibody as it reads on SEQ ID NO: 4; classified in Class 424, subclass 130.1.

XV. Claim 28, drawn to a method of providing trophic support with nucleic acid as it reads on SEQ ID NO: 2; classified in Class 514, subclass 44.

XVI. Claim 28, drawn to a method of providing trophic support with nucleic acid as it reads on SEQ ID NO: 2; classified in Class 514, subclass 44.

XVII. Claim 28, drawn to a method of providing trophic support with a protein as it reads on SEQ ID NO: 2; classified in Class 514, subclass 44.

XVIII. Claim 28, drawn to a method of providing trophic support with a protein as it reads on SEQ ID NO: 4; classified in Class 514, subclass 44.

XIX. Claim 25, drawn to a method of modulating with nucleic acid (SEQ ID NO: 2), classified in Class 514, subclass 44.

XX. Claim 25, drawn to a method of modulating with nucleic acid (SEQ ID NO: 4), classified in Class 514, subclass 44.

XXI. Claims 27 and 31-34, drawn to a method of treating with a composition comprising a nucleotide sequence as it reads on an anti-sense construct (SEQ ID NO: 2), classified in Class 514, subclass 44.

XXII. Claims 27 and 31-34, drawn to a method of treating with a composition comprising a nucleotide sequence as it reads on an anti-sense construct (SEQ ID NO: 4), classified in Class 514, subclass 44.

XXIII. Claims 27 and 31-34, drawn to a method of treating with a composition comprising a nucleotide sequence as it reads on a ribozyme (SEQ ID NO: 2), classified in Class 514, subclass 44.

XXIV. Claims 27 and 31-34, drawn to a method of treating with a composition comprising a nucleotide sequence as it reads on a ribozyme (SEQ ID NO: 4), classified in Class 514, subclass 44.

XXV. Claims 27 and 31-34, drawn to a method of treating with a composition comprising a nucleotide sequence as it reads on a retroviral vector (SEQ ID NO: 2), classified in Class 514, subclass 44.

XXVI. Claims 27 and 31-34, drawn to a method of treating with a composition comprising a nucleotide sequence as it reads on a retroviral vector (SEQ ID NO: 4), classified in Class 514, subclass 44.

5. Groups I-VI are different products. Nucleic acids, polypeptides, and antibodies to the polypeptides differ with respect to their structures and physicochemical properties; therefore each product is patentably distinct.

6. Groups VII-XXVI are different methods. A method of modulating, a method of diagnosing, and a method of providing support differ with respect to ingredients, method steps, and endpoints; therefore, each method is patentably distinct.

7. (Groups I and IX/XV/XIX/XXI/XXIII/XXV), (Groups II and X/XVI/XX/XXII/XXIV/XXVI), (Groups III and XI/XVII), (Groups IV and XII/XVIII), (Groups V and VII/XIII), and (Groups VI and VIII/XIV) are related as product and process of using. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)).

In the instant case, the nucleotide sequences of Groups I and II could be used as immunogens, in addition to the methods of modulating, treating, and diagnosing recited.

In the instant case, the polypeptide of Groups III and IV could be used to make antibodies, in addition to the methods of modulating, treating, and diagnosing recited.

In the instant case the antibody of Groups V and VI can be used for affinity purification, in addition to the methods of modulating, treating, and diagnosing recited.

8. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Species Election

9. This application contains claims directed to the following patentably distinct species of the claimed Inventions XXI-XXVI: wherein the condition is one from those listed in claim 31.

These species are distinct because the pathological conditions differ in etiologies and therapeutic endpoints; thus each condition represents patentably distinct subject matter.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 27 is generic.

10. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

11. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

12. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Megan Jamroz whose telephone number is (703) 308-8365. The examiner can normally be reached Monday through Friday from 8:00 AM to 4:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

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October 29, 2001

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